Exhibit 10

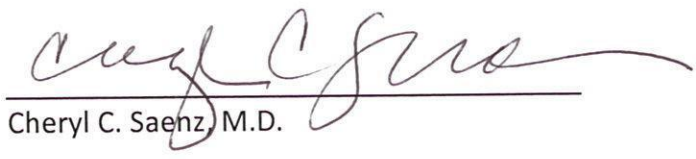
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION PASQUALINA RAUSA, Plaintiff, v. JOHNSON & JOHNSON, et al., Defendants.	MDL NO. 16-2738 (FLW) (LHG) Civil Action No.3:18-cv- 17586-FLW-LHG

EXPERT REPORT OF CHERYL C. SAENZ, M.D.

Case-specific opinions regarding Ms. Pasqualina Rausa

Date: May 28, 2024



Cheryl C. Saenz, M.D.

Diagnosis and Treatment of Ovarian Cancer

Pasqualina Rausa was born on April 10, 1955. On February 8, 2018, Ms. Rausa presented to Dr. Highly, at Duke Health for an annual gynecologic examination. At that time, she stated that she had bleeding after douching for a couple of months. She stated that she douches after intercourse, and she had also noticed an increase in discharge after intercourse. Her pelvic examination was normal, but Dr. Highly commented that it was limited by the patient's habitus.[1] Ms. Rausa's BMI at that time was 36.7. Dr. Highly recommended that Ms. Rausa stop douching as it was not helping with hygiene. She instructed Ms. Rausa that if the bleeding persisted after she ceased douching, that she should contact the doctor for further evaluation. In April 2018, Ms. Rausa presented to the office of her primary care physician, Cecilia House, D.O., with complaints of back pain and vaginal bleeding. She reported that the vaginal bleeding had been ongoing since February 2018. A pelvic ultrasound was ordered and performed on April 13, 2018. Findings on that study included an endometrial stripe of 9mm and 2 uterine masses, as well as a right ovary measuring 9.9*7.2*6.8 cm and a left ovary measuring 8.8*5.4*7.5 cm. The endometrium was interpreted as being "double thickness" and possibly consistent with hyperplasia versus carcinoma.[2] Further, she was noted to have bilateral enlarged ovaries with multiple small simple and complex peripheral ovarian cysts, which was interpreted as an unusual appearance for a post-menopausal female. At this juncture, she was referred to a general gynecologist, Dr. Nwosa. She then underwent an office hysteroscopy with dilatation and curettage on April 17, 2018. Pathology on the endometrial biopsy revealed proliferative phase glands with breakdown and no atypia or hyperplasia.[3] Ms. Rausa was then referred for a pelvic MRI which was performed on May 1, 2018, and findings included enlarged ovaries with bilateral complex solid and cystic ovarian masses concerning for bilateral cystic ovarian malignancy. PET/CT scan was performed on May 9, 2018, confirming the presence of two dominant ovarian masses with abnormal FDG activity highly suspicious for malignancy with a small amount of free fluid in the pelvis.[4]

On May 3, 2018, Ms. Rausa was seen for her initial consultation by Dr. Shazia Bashir, a gynecologic oncologist, who recommended that she be taken to the operating room for surgical exploration. On June 13, 2018, Dr. Bashir performed a laparoscopy which was converted to an exploratory laparotomy with total abdominal hysterectomy, bilateral salpingo-oophorectomy, omentectomy, pelvic and para-aortic lymph node dissection, peritoneal biopsies and optimal debulking. Final pathology revealed a high-grade serous carcinoma involving bilateral ovaries with metastases to the serosal surface of the uterus, as well as microscopic spread to the omentum. Additionally, the ascitic fluid was positive for malignant cells. As a result of the surgical staging procedure, Ms. Rausa was diagnosed with Stage IIIA high-grade serous ovarian cancer. These findings were confirmed by Baptist Health on June 13, 2019, and the pathologist at Baptist Health also commented that there were malignant cells found on the surface of the

[1] RausaP-DUHSMR-00004
[2] RausaP-AMGSVPEMR-56
[3] RausaP-AMGSVPEMR-57
[4] RausaP-AMGSVPEMR-55

right fallopian tube. The diagnosis was later confirmed again by the Mayo Clinic affiliate in Florida on June 25, 2019. Based on these pathological findings, Dr. Bashir recommended that Ms. Rausa receive six cycles of chemotherapy. Ms. Rausa was 63 years old at the time of her diagnosis.

Ms. Rausa initiated her chemotherapy treatments on July 3, 2018. Her first two cycles of chemotherapy consisted of paclitaxel and carboplatinum delivered intravenously. Overall, she tolerated the chemotherapy treatments well. However, after experiencing profound neutropenia with cycle one, she received a 25% reduction in the dose, and then each treatment was followed by injection with granulocyte colony stimulating factor. Dr. Bashir placed an intraperitoneal port in Ms. Rausa on July 9, 2018, and for cycles three and four, Ms. Rausa received a combination of intravenous and intraperitoneal chemotherapy. At some juncture, the intraperitoneal port flipped and could not be accessed and the soft tissues around the port became infected. Ms. Rausa had the intraperitoneal port removed in September 2018, and her last two cycles of chemotherapy were administered intravenously. She completed her 6th cycle of chemotherapy on October 16, 2018. Her chemotherapy treatment was prescribed by Dr. Bashir, but when Dr. Bashir moved, Ms. Rausa transferred her care to Dr. Colon-Otero, at the Mayo Clinic affiliate in Florida.

Ms. Rausa remained in remission from her ovarian cancer diagnosis for 3 ½ years, until March 11, 2022, when a CT scan was performed that revealed increased size of multiple lymph nodes in the upper abdomen, the retroperitoneum and in the pelvis. She underwent a confirmatory biopsy with endoscopic ultrasound guidance on March 18, 2022. She was advised by Dr. Colon-Otero to start chemotherapy with gemcitabine and cisplatin and received six cycles of treatment from April 6-August 9, 2022. An interval CT scan in June 2022 revealed a good response to treatment; however, a follow-up scan obtained in October 2022 revealed progression of disease. She was then started on daily oral cyclophosphamide with IV bevacizumab every 3 weeks, and continued this treatment through March 2023. In May 2023, she had imaging studies, which demonstrated an increase in the size and number of lymph nodes in her small bowel mesentery. As a result, pembrolizumab was added to her treatment regimen. She has remained on these three agents through August 2023, and a CT scan on August 15 demonstrated a decrease in the size of the mesenteric lymph nodes and no new disease. The plan as of that date was to continue the current regimen as her disease was responding to the treatment.

Clinical Cancer Genetics

Ms. Rausa denies any specific cancer family history. She herself, however, did have a colonoscopy on May 23, 2019, at which time polyps were removed and the pathology was interpreted as "fragments consistent with hyperplastic polyps."[5] Additionally, her father died in a car accident when she was only 8 years old, and as her father's family all lives in Italy, she does not have any health history from her paternal side.

[5] RausaP-ColonOteroG-00481

Based on her personal history of ovarian cancer and consistent with NCCN guidelines, Ms. Rausa's risk of being a gene mutation carrier was high enough to justify genetic testing. Dr. Bashir ordered germline genetic testing for Ms. Rausa through genpath, and her results were received on August 9, 2018. Ms. Rausa was found to be negative for a germline mutation in 45/46 genes tested, however, a variant of uncertain significance was detected in the FH gene. This mutation is thought to be deleterious, however, it is unclear if it is a benign or pathogenic mutation based on evidence available at the time of her testing.[6] In June 2019, Dr. Colon-Otero ordered molecular profiling of Ms. Rausa's tumor from Foundation One.[7] The analysis revealed mutations in *TP53* and *ATRX* with amplification of *AKT2*, but no evidence of homologous recombination deficiency. Later, In May 2022, she had additional somatic testing through Myriad, My Choice CDx, confirming that her tumor did not demonstrate genomic instability, meaning that she is not likely to benefit from maintenance therapy with PARP inhibitors. In December 2022, her tumor was assayed for FOLR1 receptor and the cells had only 30% expression, meaning that it was unlikely that her cancer would respond to mirvetuximab soravtansine-gynx (Elahere).

Ms. Rausa never actually had a consultation with a medical genetics counselor. This is an unfortunate lapse in her medical care, as genetic counselors are responsible for not only interpreting the impact of positive results to patients, but also negative results. Had Ms. Rausa seen a genetics counselor, she would have inevitably been informed that because the genetic basis, if any, of her ovarian cancer has not been identified, this negative result does <u>not</u> necessarily mean that her cancer was sporadic (i.e., not attributable to an inherited predisposition). This is because of two important limitations of the test. First, not all inherited predisposition to cancer is attributable to the 46 genes that she was tested for. Research has identified other genes that when mutated can increase one's risk of cancer. Second, a small percentage of mutations in genes tested by this panel may be missed by current technology.

Past Medical History

- Non-insulin dependent diabetes mellitus
- Hypertension
- Hyperlipidemia
- Depression and anxiety
- Asthmatic bronchitis
- Diverticulosis
- Hyperplastic colonic polyps
- Obesity
- Obstructive sleep apnea
- Degenerative joint disease
- Left ankle tendon tear

[6] RausaP-GDXMR-00016
[7] RausaR-FMIMR-00002

Past Surgical History

- Bilateral tubal ligation, 1988
- Breast biopsy, 2004
- Bilateral knee replacement, 2010Office hysteroscopy with dilatation and curettage, 2018
- Laparoscopy converted to exploratory laparotomy TAH/BSO, omentectomy, pelvic and para-aortic lymph node dissection, peritoneal biopsies and optimal debulking, 2018
- Placement and removal of intraperitoneal port, 2018
- Robotic-assisted ventral incisional hernia repair with mesh, 2020

Obstetrical/Gynecologic History

- Menarche at age 11
- Menopause at ~ age 56 (although some of her medical records report ~ age 48)[8]
- G2P2 with first child at age 30
- Breastfeeding – none
- Oral contraceptives – ~ 2 months
- Douching after periods and after intercourse
- Hormone replacement therapy – none
- Bilateral tubal ligation 1988

Summary

I have performed a thorough review of Ms. Rausa's medical records, the depositions of Pasquelina Rausa, Gerardo Colon-Otero, M.D., Daniel Rausa, D.O., Nicholas Rausa and Joseph Rausa, as well as the Plaintiff Profile Forms, expert reports of Drs. Godleski and Clarke-Pearson, and the depositions of Dr. Clarke-Pearson.

Ms. Rausa was diagnosed with Stage IIIA high grade serous carcinoma of bilateral ovaries in June 2018. With appropriate surgery and an optimal debulking by Dr. Bashir, followed by aggressive chemotherapy, Ms. Rausa's cancer entered remission for 3 ½ years but ultimately recurred in her lymph nodes in March 2022. Since that time she has been treated with several different therapeutic regimens. As of the last medical record in August 2023, her cancer was responding to a combination of chemotherapy, angiogenesis inhibitor, and immunotherapy. Even though Ms. Rausa had negative germline testing of 45 genes with a variant of uncertain significance in the FH gene on the genpath panel, there is still a possibility that Ms. Rausa is carrying a germline mutation that we have yet to identify that contributed to her development of ovarian cancer. Most likely, Ms. Rausa's ovarian cancer developed sporadically, with no distinct causal mechanism that can be identified.

[8] RausaP-MemorialHospMR-00023

In his report and in testimony, Dr. Clarke-Pearson states that he has performed a differential diagnosis and concluded that Ms. Rausa's high-grade serous ovarian cancer was caused by the perineal application of talc. But there is no reliable way to rule in talc as a cause of ovarian cancer and he did not reliably rule out other risk factors that potentially led to the development of her ovarian cancer. The reality is that in most cases, we simply do not know what the most likely cause was of a woman's disease. That is the case with Ms. Rausa. The answer is certainly not talc.

Of note, in February 2019, Dr. Clarke-Pearson testified that we can never really know what causes ovarian cancer in any individual woman, stating:

A. What I think I understand your question being, if we can't identify a gene mutation, then we don't know what caused it. Is that what you're asking me?

Q. Yes.

A. Then the answer would be, yes, we don't know.[9]

Nonetheless, in deposition testimony in 2021, Dr. Clarke-Pearson stated that he can now determine the cause of an individual woman's ovarian cancer, retracting his prior testimony by stating, "Well, that was my answer at the time."[10] Yet even in that deposition, he almost immediately retreated to his prior opinion, agreeing that "there is no way to tell, in an individual woman who used talc, whether she got ovarian cancer because of her talc use" or would have developed it anyway. [11]

Additionally problematic are Dr. Clarke Pearson's opinions where he cites to Dr. Godleski's report to support his contention that the perineal application of talc caused Ms. Rausa to develop ovarian cancer. Dr. Godleski reports that he found 25 birefringent particles in the 46 tissue slides that he examined. Dr. Godleski further claims that two of those particles likely represent talc, one in Ms. Rausa's left external iliac lymph node and one in a left para-aortic lymph node. Of note, neither of these organs had cancer in them. The cancer was found solely in Ms. Rausa's ovaries, omentum, pelvic washings and on the surface of the uterus. There was no talc found in the tissue blocks of Ms. Rausa's ovaries. Notably, there is no evidence of an inflammatory response in the areas were Dr. Godleski states he found talc particles.

Dr. Clarke-Pearson has also repeatedly testified that he can use an odds ratio from a study to attribute a proportion of a plaintiff's cancer to her talc use and reach a conclusion on specific causation. This is a misapplication of epidemiological principles. A relative risk, even if it is affected by bias or other limitations, is not directly translatable to an individual's attributable risk of a cancer diagnosis.

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[9] February 4, 2019 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 94, lines 4-11.
[10] August 26, 2021 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 215, line 2.
[11] August 26, 2021 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 248 line 7-p. 249, line 2.

Conclusion

While Ms. Rausa states that she used baby powder daily from 1968-2018 for hygiene purposes, there is no credible scientific data to support the conclusion that the talc contributed to her development of ovarian cancer. The peer-reviewed scientific literature, nationally recognized and respected healthcare organizations (NCI, CDC, ACS, FDA), and the professional societies (SGO, ACOG) to which I belong, all maintain the position that talc does not cause ovarian cancer. All of the opinions herein are to a reasonable degree of medical probability. In addition, all of the general causation opinions contained in my General Expert Report dated May 21, 2024 are also incorporated herein.

MATERIALS RELIED ON AND CONSIDERED BY DR. CHERYL SAENZ

PLAINTIFF PROFILE FORM

1. 08/23/2020 Plaintiff Profile Form of Pasqualina Rausa

DEPOSITION TRANSCRIPTS

1. 02/04/2019 Deposition Transcript of Daniel Clarke-Pearson, MD
2. 01/27/2021 Deposition Transcript of Pasqualina Rausa
3. 03/02/2021 Deposition Transcript of Gerardo Colon-Otero, MD
4. 04/26/2021 Deposition Transcript of Daniel Rausa, DO
5. 05/11/2021 Deposition Transcript of Nicholas Rausa
6. 05/12/2021 Deposition Transcript of Joseph Rausa
7. 08/26/2021 Deposition Transcript of Daniel Clarke-Pearson, MD (Vol. 1)
8. 08/27/2021 Deposition Transcript of Daniel Clarke-Pearson, MD (Vol. 2)
9. 01/17/2024 Deposition Transcript of Daniel Clarke-Pearson, MD
10. 03/08/2024 Deposition Transcript of Daniel Clarke-Pearson, MD

EXPERT REPORTS

1. 06/21/2021 Expert Report of John Godleski, MD
2. 07/02/2021 Expert Report of Daniel Clarke-Pearson, MD
3. 11/15/2025 Amended Rule 26 Expert Report of Daniel Clarke-Pearson, MD

MEDICAL RECORDS

1. Ascension Medical Group St Vincent (RausaP-AscensnMedGrpStVincentsPrimCareMR-00004-00072; RausaP-AMGSVPEMR-00005-00063; RausaP-AscensionSt.VincentPath-00001-00022; RausaP-AMGSVPEPB-00012-00030)
2. Baptist Medical Center Jacksonville (RausaP-BMCJMR-00001-00067; RausaP-BMCJMR-00077-00086; RausaP-BMCJMR-00096-00097; RausaP-BMCJMR-00096-00097; RausaP-BMCJMR-00099-00111; RausaP-BMCJMR-00113-00125)
3. Bon Secours Health System (RausaP-BSHSIMR-00001-00057)
4. Cancer Specialists of North Florida (RausaP-CSNF-00004-00024, RausaP-CSNFMR-00065-00070; RausaP-CSNFRadMAT-00001-00016)
5. Cancer Specialists of North Florida – Fleming Island (RausaP-CSNFFIMR-00070-00188)
6. Cisca Pulmonary Critical Care (RausaP-CPCCMR-00001-00012)
7. Clarkstown Medical Associates (RausaP-CMAMR-00001-00134; RausaP-CMAPB-00044-00184)
8. Conolo-Otero, Gerardo, MD (RausaP-ColonOteroG-00009-00675)

9. Crystal Run Healthcare (RausaP-CRHLLPMR-00010-00018; RausaP-CRHLLPRAD-00001-00008)
10. Diabetes & Endocrinology Consultants (RausaP-DECMR-00001-00050)
11. Duke University Health System (RausaP-DUHSMR-00001-00013)
12. Florida Specialty Pharmacy (RausaP-CSNF-00001-00003)
13. Foundation Medicine (RausaP-FMIMR-00001-00037; RausaP-FMIPB-00001-00012; RausaP-FMIPB-00019-00027; RausaP-FMIMR-00038-00075)
14. Gene DX (RausaP-GDXMR-00001-00021)
15. Genpath (RausaP-GenPathMR-00001-00016)
16. Good Samaritan Hospital (RausaP-GSHRadMAT-00001)
17. Helen Hayes Hospital (RausaP-HHHPB-00001-00009)
18. Hospital for Special Surgery Medical Records Department (RausaP-HSSMR-00001-00099)
19. Hostin, Helen, MD (RausaP-HostinH-00001-00018)
20. Hudson Valley Radiology Associates (RausaP-HVRAMR-00001-00030)
21. Bruce Levitt, MD (RausaP-LevittB-00001-00005; RausaP-LevittB-00086-00103)
22. Mayo Clinic (RausaP-MCMR-00010-00127, RausaP-MCMB-00047-00050)
23. Mayo Clinic Oncology (RausaP-MCOMR-00010-00545; RausaP-MCOMR-00553-00722, RausaP-MCOPB-00047-00063)
24. Mayo Clinic – Plaintiff Produced (PRAUSAPL-MAYOC-00092-00591; PRAUSAPL-MAYOC-01092-01591; PRAUSAPL-MAYOC-01592-02091; PRAUSAPL-MAYOC-02092-02323; PRAUSAPL-MAYOC-02327-02339; PRAUSAPL-MAYOC-02345-02348; PRAUSAPL-MAYOC-02350-02354; PRAUSAPL-MAYOC-02356-02366; PRAUSAPL-MAYOC-02378; PRAUSAPL-MAYOC-02389-02511; PRAUSAPL-MAYOC-02518-02549; PRAUSAPL-MAYOC-02553-02591; PRAUSAPL-MAYOC-03092-03112; PRAUSAPL-MAYOC-03118-03151; PRAUSAPL-MAYOC-03156-03158; RAUSAPL-MAYOC-03164-03338; PRAUSAPL-MAYOC-03340-03361; PRAUSAPL-MAYOC-03365-03377; PRAUSAPL-MAYOC-03379-03412; PRAUSAPL-MAYOC-03414-03478; PRAUSAPL-MAYOC-03482-03483; PRAUSAPL-MAYOC-03490-03610; PRAUSAPL-MAYOC-03611-03647)
25. Memorial Hospital (RausaP-MemorialHospMR-00001-00149; RausaP-MHRad-00001-00003; RausaP-MHPB-00016-00026)
26. Navsta Norfolk BHC (RausaP-NNBHCMR-00001-00022)
27. Plaintiff Produced Medical Records (PRAUSAPL- AMG-000001-38; PRAUSAPL-00027-00124; PRAUSAPL-00125-00151; PRAUSAPL-AMGSVPC-000001-6; PRAUSAPL-CMA-000001-000117; PRAUSAPL-CRHWN00001-000003; PRAUSAPL-CSNFLSP-000001-114; PRAUSAPL-DRBASHIR-00001-83; PRAUSAPL-DRHOSTIN-000001-11; PRAUSAPL-DRHOUSE-000001-000120; PRAUSAPL-MCRO-000001-1126; PRAUSAPL-SVRHBLOCK00001; PRAUSAPL-SVSHPATH-000001-28)
28. Publix Pharmacy (RausaP-PPCO-00001-00008; RausaP-PPCO-00017-00021)
29. Quest Diagnostics (RausaP-QDIPB-00001-00007)
30. Rockland Neurological Associates (RausaP-RNAPB-00001-00046)

31. Sharon Saka Associates (RausaP-SSAMR-00001-00012)
32. St. Vincent's Medical Center (RausaP-SVMCSMR-00001-01199; RausaP-SVMCRMR-00001-00073; RausaP-SVMCRPath-00001-00025; RausaP-SVMCSRad-00007-00013; RausaP-SVMCSRad-00001-00006; RausaP-SVMCSRad-00014-00031; RausaP-SVMCSRadMAt-00008-00024; RausaP-SVMCRPath-00026-00029)
33. St. Vincent's OBGYN Southside (RausaP-SVOBGYNSMR-00001-00040)

ADDITIONAL MATERIALS

Saed Confidential Documents (SAED_SEPT222021_SUPPL_000001-399)